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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,186	02/26/2004	Kenan C. Murphy	UMY-046	9606

959 7590 09/22/2005

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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,186	MURPHY, KENAN C.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to a nucleic acid molecule comprising nucleotide sequences encoding bacteriophage recombinase and anti-recombinase functions and a recombinant organism comprising the nucleotide sequence, classified in class 435, subclass 325.

II. Claims 27-32, drawn to a method of promoting efficient recombination in a microorganism comprising the use of a vector, classified in class 435, subclass 478.

III. Claims 33-37, drawn to a method for determining whether a bacterial gene is a potential drug target, classified in class 424, subclass 9.2.

IV. Claim 38, drawn to a method of cloning a potential vaccine antigen, classified in class 424, subclass 93.2.

V. Claim 39, drawn to a vaccine, classified in class 424, subclass 184.1.

VI. Claims 41-43, drawn to a method of producing an attenuated pathogenic microorganism and the vaccine

comprising the attenuated pathogenic microorganism, classified in class 424, subclass 265.1.

Note: Claim 40 provides for the use of a recombinant organism in a manufacture of a vaccine. However, since the claim is not directed to a statutory class of invention (method, process, product, machine), this claim has not been included among the inventions listed above.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids and recombinant organisms comprising the nucleic acids of Group I and the vaccines of Group V and VI are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups. The nucleic acids of Group I can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated vaccines of Group V and VI. The recombinant organisms comprising the nucleic acids of Group I are also chemically, biologically and functionally distinct from the vaccines of Group V and VI and thus one does not render the other obvious. The vaccines of Group V and VI

require the presence of a potential vaccine antigen (Group V) or attenuated pathogenic microorganism (Group VI) not required of the recombinant organism of Group I. The antigen or attenuated pathogenic microorganism can be isolated from cells or organisms, made synthetically and/or are self-replicating without the need for the nucleic acids or recombinant organisms of Group I. Similarly, the vaccines of Groups V and VI are derived from different methods and products comprising an attenuated pathogenic microorganism in the case of Group VI and a cloned microorganism with a vaccine-antigen gene in the case of Group V.

Furthermore, searching the inventions of Group I, V and VI together would impose a serious search burden. In the instant case, the search of the nucleic acids and recombinant organisms of Group I and the vaccines of Group V and VI are not coextensive. Each of the inventions from Groups I, V and VI would require a search based on their identifying characteristics: a nucleic acid sequence encoding a recombinase function or a recombinant organism comprising said nucleic acid sequence (Group I), a potential vaccine antigen (Group V) and an attenuated pathogenic microorganism (Group VI). The inventions of Groups I, V and VI have a separate status in the art as shown by their different classifications. As such, it would be

burdensome to search any of the inventions of Groups I, V and VI together.

Inventions of Groups II-IV and VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-IV and VI comprise steps which are not required for or present in the methods of the other groups: promoting efficient recombination in a microorganism (Group II), determining whether a bacterial gene is a good drug target(Group III), cloning a potential vaccine antigen (Group IV) and producing an attenuated pathogenic microorganism (Group VI). The end results of the methods are different: efficient recombination in a microorganism (Group II), bacterial genes which are good drug targets (Group III), a clone of a potential vaccine antigen (Group IV) and an attenuated pathogenic microorganism and a vaccine comprised of the attenuated pathogenic microorganism (Group VI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Furthermore, searching the inventions of Groups II-IV and VI would impose a serious search burden. In the instant case, the search of the methods promoting efficient recombination in a

microorganism (Group II), determining whether a bacterial gene is a good drug target(Group III), cloning a potential vaccine antigen (Group IV) and producing an attenuated pathogenic microorganism (Group VI) are not coextensive. The inventions of Groups II-IV and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any of the inventions of Groups II-IV and VI together.

Inventions of Group I and Groups II-IV and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of using, as evidenced by the inventions of Groups II-IV and VI which comprise very different methods which utilize a vector comprising a nucleotide sequences encoding bacteriophage recombinase function or an organism with said vector.

Furthermore, searching the invention of Group I with any of the inventions from Groups II-IV and VI would impose a serious search burden. In the instant case, the search of the nucleic

acids and recombinant organisms comprising the nucleic acids of Group I would not be coextensive with methods promoting efficient recombination in a microorganism (Group II), determining whether a bacterial gene is a good drug target(Group III), cloning a potential vaccine antigen (Group IV) and producing an attenuated pathogenic microorganism (Group VI). The inventions of Group I and Groups II-IV and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Group I with any of the inventions of Groups II-IV and VI.

Except for the specific relationships described above, the product invention of Group V and method inventions of Groups II-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the product of Group V is not used in or made by the methods of Groups II-IV and VI.

Furthermore, searching the invention of Group V with any of the inventions of Groups II-IV and VI would impose a serious search burden. In the instant case, the search for a vaccine would not be coextensive with a search for the method of

promoting efficient recombination in a microorganism (Group II), the method for determining whether a bacterial gene is a potential drug target (Group III), the method of cloning a potential vaccine antigen (Group IV) or the method of producing an attenuated pathogenic microorganism (Group VI). The invention of Groups V has a separate status in the art as shown by its different classification from Groups II-IV and VI. As such, it would be burdensome to search any of the inventions of Groups II-IV and VI together.

Conclusion

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application

Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at

this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

September 16, 2005

TERRY MCKELVEY
PRIMARY EXAMINER